

#### FOOD AND DRUG ADMINISTRATION

#### AN EQUAL OPPORTUNITY EMPLOYER

## VACANCY ANNOUNCEMENT

#### FDA IS SMOKE-FREE

**Announcement Number:** FDA-8-4029

**Opening Date:** August 17, 1998

Closing Date: August 31, 1998

**Position Title:** Veterinary Medical Officer

Series & Grade: GS-701-13

**Promotion Potential:** None

**Salary Range:** GS-13 \$55,969 - \$72,758 per annum

**Area of Consideration:** Government Wide

**Type of Appointment:** Career/Career Conditional

**Relocation expenses:** Will not be paid

Organization, Duty Location: DHHS, FDA, Center for Veterinary Medicine (CVM), Office of the New Animal Drug Evaluation,

Quality Assurance Support Team, Rockville, MD, Metro Park North 2 Building

Commissioned Corps candidates may apply.

## **JOB SUMMARY:**

The incumbent serves as a Veterinary Medical Officer on the Quality Assurance Support Staff in the Office of New Animal Drug Evaluation. This staff is responsible for administering the generic animal drug program and quality assurance of pre-clearance actions. Knowledge of the safety and effectiveness of drug products used in veterinary practice, including such phenomenon as antimicrobial resistance, and target organ toxicity. Ability to bridge science with statutory changes, including statutory changes such as the (Generic Animal Drug and Patent Term Restoration Act of 1988) and Animal Drug Availability Act of 1996, and the related differences in effectiveness data requirements, and such policies pertaining thereto. **Specific duties include:** 

Prepares written veterinary medical reviews, including label reviews and bioequivalence reviews. Manages the administrative and scientific review of generic investigational new animal drug (JINAD) files and abbreviated new animal drug applications (ANADA). Reviews new animal drug product labels to assure that all indications for use are supported by substantial evidence of safety and effectiveness to the target animal species.

Comments on protocols for bioequivalence studies including blood level studies, clinical end-point studies, and related experimental design features.

Concurs with human food safety decisions as regards appropriate withdrawal times for investigational food animals intended for slaughter for food. Reviews authorization letters for adherence to agency policies and regulations to assure protection of the public health from unsafe drug residues in meat, milk and eggs.

Assists in the development of responses to Suitability Petitions (Citizen Petitions), good guidance practices (GGPs), and other generic drug policy letters and decisions.

Recommends policy changes for the generic animal drug program.

Meets with drug sponsors and provides guidance to sponsors on numerous center policies and procedures.

Recommends steps to assure that extra-label use of new animal drugs, including generic animal drugs, will not compromise public safety to human health.

Communicates with drug sponsors to enhance new animal drug availability to livestock producers, veterinarians, and consumers. Maintains proficient computer skills to enhance the efficiency of the regulatory process, including the electronic submissions of JINADs and ANADAs and the subsequent review and achievement of such review via electronic media.

## **OUALIFICATIONS:**

## **VETERINARY MEDICAL OFFICER, GS-701**

Applicants must possess a degree of Doctor of Veterinary Medicine (or equivalent degree) at a school approved or accredited by (a) the American Veterinary Medical Association (AVMA), (b) a State department of education, or (c) a State Board of Veterinary Medical Examiners.

Graduates of foreign veterinary medical schools who do not meet the requirements specified above must furnish proof of (a) graduation from a veterinary medical school, (b) comprehension of and ability to communicate in the English language, and (c) passage of the written examination in veterinary medicine of the Educational Commission for Foreign Veterinary Graduates of the U.S. National Board of Veterinary Medical Examiners. Proof of English language proficiency may be met by (1) achieving a total score on the Test of English as a Foreign Language at least 550 with a listening comprehension score of at least 60 points, (2) earning an advanced degree (i.e., an M.S. or PhD.) at a U.S. college or university, or (3) graduating from a U.S. or Canadian English speaking high school. The following are exceptions to these requirements:

Veterinarians who qualified between 1965 and 1972, who hold certificates under the program of the Educational Commission for Foreign Graduates.

Candidates must have 52 weeks of specialized experience equivalent to the GS-12 grade level in the Federal service.

Specialized experience is experience which is typically in or directly related to the work of the position.

In addition to the above qualifications candidates must posses the following selective factor:

EXPERIENCE IN EVALUATING ANIMAL DRUG SAFETY AND EFFECTIVENESS DATA FOR FOOD AND NON-FOOD ANIMALS IN ACCORDANCE WITH STANDARDS MANDATED BY THE FFD&C ACT AND ATTENDANT FEDERAL REGULATIONS AND POLICIES, SPECIFICALLY AS RELATED TO THE ANIMAL DRUG AVAILABILITY ACT (ADAA) OF 1996, THE GENERIC ANIMAL DRUG AND PATENT TERM RESTORATION ACT (GADPTRA) OF 1988.

Candidates must meet all qualification requirements, including time-in-grade, within 30 days after the closing date.

## **EVALUATION METHOD:**

Candidates found basically qualified will be further evaluated by determining the extent to which their work or related experience, education, training, awards, etc., indicate their possession of the knowledge, skills, and abilities (KSA's) described below.

- 1. Knowledge of the practice of food animal and non-food animal medicine principles and theories.
- 2. Ability to communicate findings in writing.
- 3. Ability to communicate findings orally.
- 4. Ability to review and evaluate data.
- 5. Knowledge of laws and regulations relating to animal drug approvals.

#### **HOW TO APPLY:**

A. Candidates may submit an Application for Federal Employment (SF-171), an Optional Application for Federal Employment (OF 612), resume, curriculum vitae, or any other written format. Your application **must** include the following information:

#### **VACANCY INFORMATION**

\*Vacancy Announcement Number, Title, Grade

#### PERSONAL INFORMATION

- \*Full legal name
- \*Mailing address
- \*Social Security Number
- \*Home and Work telephone numbers
- \*Birth Date
- \*Citizenship
- \*Reinstatement eligibility
- \*Highest Federal civilian grade held (give job series, dates held)

# **EDUCATION** (Transcripts may be substituted for most of the following)

- \*Date of high school graduation or GED
- \*Name, location and dates of each college/university attended
- \*Type of degree(s), if any, date(s) received
- \*Major field of study
- \*Total semester or quarter hours
- \*Undergraduate GPA or class rank

## **EXPERIENCE** - most relevant to this position include:

- \*Name of employer (Supervisor)
- \*Address and telephone number of employer
- \*Dates of employment (month/year)
- \*Job title
- \*Brief description of your duties and responsibilities for each job listed
- \*Average hours worked for each position if less than 40 hours per week

## **TRAINING**-To receive credit for relevant training:

\*List of course titles, dates, number of hours attended and name(s) of the institution(s)

# HONORS AND AWARDS-If relevant to position for which applying

\*Description of honors and/or awards along with dates acquired

#### **SKILLS/SPECIAL QUALIFICATIONS**-If relevant to the position for which applying

- \*Language skills (other than English)
- \*License(s) and date(s) acquired
- \*Typing Speed/Words Per Minute (WPM)
- \*Dictation Speed/WPM
- B. Additional information/completed forms to be submitted, if checked; failure to submit requested information/documents may result in nonconsideration or a lower rating in the evaluation process.
- \_X\_ Written response to the knowledge, skills and abilities
- \_\_\_ If claiming veterans' preference, see additional information on this form
- \_X\_ College transcripts or list of courses, including title, credit hours and grade for each course and/or changing occupational series; see additional information on this form for foreign education\*
- \_X\_ Current federal employees most recent performance appraisal/evaluation
- \_X\_ Current **and** former federal employees a copy of most recent complete SF-50, Notification of Personnel Action, to verify status

<sup>\*</sup>Qualifying education gained at college and universities in foreign counties <u>must</u> be evaluated in terms of it equivalency to that acquired in American colleges and universities. Applicants educated in whole or in part in foreign countries must submit sufficient evidence, including transcripts, to an accredited private organization for an equivalency evaluation. A letter containing the results **MUST** accompany the application package.

Applicant Background Survey: Please return the Background Survey with your application. This information you provide is used for statistical purposes. The return of this form is voluntary. Failure to return this form will have no impact on your consideration for this position.

**ADDRESS:** Food and Drug Administration

Office of Human Resources and Management Services

**Attn: Mary Goodson** 

Room 211, Metro Park North I, HFA-423

7520 Standish Place Rockville, MD 20855

Additional forms and information may be obtained from the address above or by calling Mary Goodson at (301) 827-7332 or the Job Information Office at (301) 827-4070 (Voice/TTY).

If you would like a copy of the vacancy announcement faxed to you, please call FAXBACK at (301) 827-4287 or to have a copy mailed to you, please call the Job Information Line at (301) 443-1969. For employment information, visit our websites at http://fda.gov (click on "Index" and "Job Openings"). FDA employees can also access the FDA Intranet at http://ohrms.fda.gov (click on "Vacancies").

Applications received become the property of the Office of Human Resources and Management Services and will not be returned.

Applications submitted in postage paid Government envelopes will not be accepted.

ALL APPLICATION MATERIAL MUST BE POSTMARKED OR RECEIVED BY THE CLOSING DATE OF THIS ANNOUNCEMENT.

All applicants will receive equal consideration without regard to race, religion, color, national origin, sex, disability, sexual orientation, political affiliation, age (with authorized exceptions) or any other non-merit factor.

Vietnam era veterans, disabled veterans, individuals with disabilities, and other individuals eligible for special appointing authorities are encouraged to apply.

This is a competitive vacancy, open to all United States citizens, advertised under examining authority delegated to the Food and Drug Administration by the U.S. Office of Personnel Management.

**CONDITION OF EMPLOYMENT:** Certain positions within the FDA are subject to strict restrictions on financial holdings (FDA regulated financial holdings). To determine whether this position is affected, applicants are advised to seek additional information during the interview process prior to accepting such a position.

Selection priority will be given to the best qualified CTAP applicants.

Surplus or Displaced Employees in the Department of Health And Human Services (DHHS) Requesting Special Selection Priority Consideration Under The Career Transition Assistance Program (CTAP)

**If you are currently a DHHS employee** you may be entitled to special priority selection under the DHHS Career Transition Assistance Program (CTAP). To receive priority consideration, you must:

- 1. Be a current DHHS employee serving under an appointment in the competitive or excepted service in tenure group I or II, in receipt of (1) a Reduction in Force (RIF) specific separation notice, (2) a notice of proposed removal for declining a directed reassignment or transfer of function outside of the commuting area, (3) a Certificate of Expected Separation (CES), or (4) other official notice that indicates the employee is surplus or eligible for discontinued service retirement (DSR) or as being in a surplus organization or occupation, and the date of the separation has not passed and you are still on the rolls of DHHS. You must submit a copy of the separation notice, CES, or other official notice along with your application in order to receive special priority consideration;
- 2. Be applying for a position that is at or below the grade level of the position from which you are being separated. The position must not have a greater promotion potential than the position from which you are being separated;

- 3. Have a current (or last) performance rating of record of at least fully successful or equivalent. **This must be submitted with your application package**;
- 4. Be currently employed by DHHS in the same commuting area of the position for which you are requesting priority consideration;
- 5. Submit your application (including all required documentation) by the vacancy announcement closing date and meet all the application criteria; **and**
- 6. Be rated well qualified for the position.

"Well Qualified" means: a surplus/displaced employee must meet the minimum qualifications and eligibility requirements for the position, including any documented selective factor(s), and be rated and ranked under the same procedures as merit promotion applicants to determine the extent to which he/she possesses the knowledge, skills, and abilities (KSAs) to succeed in the position being filled. A cut-off score will be used to determine the well qualified applicant(s).

Displaced Employees Requesting Special Selection Priority Consideration Under The Interagency Career Transition Assistance Program (ICTAP)

If you are a displaced Federal employee you may be entitled to receive priority selection under the ICTAP.

To be eligible for the special selection priority, you must meet all of the following:

- (1) Be a displaced Federal employee;
- (2) Submit a copy of your current (or your last) performance rating of record of at least fully successful or equivalent;
- (3) Apply for a vacancy at or below the grade level from which you were or are being separated, that does not have a greater promotion potential than the position from which you have been or are being separated from;
- (4) Occupy, or was displaced from a position in the same local commuting area of the vacancy;
- (5) Submit an application (including all required documentation) for a specific vacancy within the time frames established on the announcement and meet all the application and eligibility criteria;
- (6) Submit proof of eligibility; and
- (7) Be rated well qualified for the position.
  - "Well Qualified "means: a displaced employee must meet the minimum qualification and eligibility requirements for the position (including any selective factors), and be rated and ranked to determine the extent to which he/she possesses the knowledge, skill, and abilities (KSAs) to succeed in the position being filled. Under merit promotion procedures, a cut-off score will be used to determine the well qualified applicant(s). Under delegated examining procedures, the displaced employee must receive a score of 90 or better to receive selection priority.

Displaced employees may submit any (one) of the following as proof of eligibility for the special selection priority:

- (1) IF separation notice, or notice of proposed removal for declining a directed reassignment or transfer of function to another commuting area;
- (2) Documentation, e.g., SF-50, Notification of Personnel Action, showing that you were separated as a result of RIF, or for declining a directed reassignment or transfer of function to another commuting area;
- (3) Official certification from an agency stating that it cannot place an individual whose injury compensation has been or is being terminated;
- (4) Official notification from O.M. that your disability annuity has been or is being terminated; or
- (5) Official notification from the Military Department or National Guard Bureau that the employee has retired under 5 U.S.C. 8337(h) or 8456.